DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

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PURGED

May 20, 1998

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 30

Mr. James Russel
President
Mersco Medical, Inc.
712 South Cliff Avenue
Sioux Falls, SD 57104

Dear Mr. Russel:

During a recent inspection of your Mersco Medical Inc. medical oxygen transfiller operation located at 1411 East Wells Avenue, Pierre, SD, our investigator found serious violations of the Current Good Manufacturing Practices (GMPs) for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 (21 CFR 211). Oxygen is a drug within the meaning of Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act). Your transfilled oxygen is adulterated within the meaning of Section 501(a)(2)(B) of the Act.

The violations observed during our inspection include but are not limited to the following:

1. Failure to calibrate instruments, apparatus, gauges, and recording devices at suitable intervals in accordance with an established written program containing specific directions, schedules, limits for accuracy and precision, and provisions for remedial action in the event accuracy and/or precision limits are not met.

For example:

(A) You are not properly calibrating your [redacted] oxygen analyzer. The oxygen used to calibrate your [redacted] is medical grade oxygen. The oxygen is not a certified laboratory gas and lacks a Certificate of Analysis.

(B) You fail to calibrate your vacuum gauge.

2. Failure to establish a written program containing specific directions, schedules, limits for accuracy and precision, and provisions for remedial action in the event accuracy and/or precision limits are not met. For example:

   (A) There is no standard operating procedure (SOP) for calibrating the thermometer.

   (B) Your SOP's do not adequately specify which gauges are to be calibrated semi-annually.

3. Failure to inspect the packaging materials to assure that packaging and labeling materials not suitable for subsequent operations have been removed. For example:

   (A) You are not always removing old lot numbers from your E cylinders during the filling operation as per your SOP's.

The above indication of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and or injunction. This is official notification that FDA expects all your locations to be in compliance.

Our investigator noted in his Establishment Inspection Report that Ms. Terry Disburg stated during the discussion of the form FDA-483 that a number of corrections to problems cited during the inspection had already been made.

Ms. Disburg has now responded to the form FDA-483 that was issued during the inspection and her response is currently under review.

Further examination of your [redacted] Calibration Log has revealed the log was reviewed by your Quality Control department on a Monday and then there was another calibration on Thursday of the same week, which was not reviewed. It also appears the calibration of the [redacted] and the QC review were performed by the same person. It is unacceptable to have one person QC their own work.

You should notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Compliance Officer Carrie A. Hoffman at the address on the letterhead.

Sincerely,

James A. Rahto
District Director
Minneapolis District

xc: Ms. Judy Blauwett
Vice President
Mersco Medical, Inc.
712 South Cliff Avenue
Sioux Falls, SD 57104

xc: Terry K. Disburg
Manager
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1411 Wells Ave
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